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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,777	03/09/2004	Eija Pirhonen	01942-00019	1657
22910	7590	03/25/2005	EXAMINER	
BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/796,777	Applicant(s) PIRHONEN ET AL.	
	Examiner Anand U. Desai, Ph.D.	Art Unit 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 21-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, drawn to claims 1-14, and 21-35 in the reply filed on December 22, 2004 is acknowledged. The traversal is on the ground(s) that it would not be over burdensome to examine groups of inventions together. This is not found persuasive because search would be burdensome. As stated in the restriction requirement, the inventions are distinct and have acquired a separate status in the art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 22, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Priority***

3. The priority date is the filing date of the current application, March 9, 2004.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on July 8, 2004 is being considered by the examiner.

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-14, and 21-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In claims 1, 13, 14, and 21, how is the pyrrolidone “arranged” with the carrier? A chemical bond to the carrier?

8. In claims 7, and 25, what is “one bioactive agent?”

9. In claim 28, how is the carrier “arranged” with the scaffold?

10. In claims 21, and 29, how does one distinguish the carrier from the scaffold if both materials are ceramic, glass ceramic, or glass material?

11. In claim 31, what is the “polymer material?”

12. Claims 3-12, and 22-35 are rejected for depending on rejected claims 1, and 21, respectively.

*Claim Rejections - 35 USC § 102*

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 3, 6-8, 10-12, 21, 22, 24-26, 28, 29, and 31-35 rejected under 35 U.S.C. 102(b) as being anticipated by Eitenmuller et al. (U.S. Patent 4,610,692).

Eitenmuller et al. disclose a sintered tricalcium phosphate ceramic implant (see U.S. Patent '692, col. 5, line 37) for filling bone cavities and for fixing bone fragments in a living body, comprising a discretely-shaped, baked porous body of tricalcium phosphate, at least one therapeutically-active ingredient impregnated into said porous body and distributed among the pores therein, and at least one coating of a biodegradable substance on at least a portion of said porous body impregnated with said therapeutically-active ingredient, wherein the therapeutically-active ingredient is selected from the group consisting of polyvinyl pyrrolidone, iodine, penicillin, cycloserin, bacitracin, nystatin, amphotericin, gentamycin, novobiocin, erythromycin, momycin, streptomycin, flucloxacilin, sulfonamide, and **mixtures thereof** (see U.S. Patent '692, claims 17, and 22). The porous body is impregnated with up to about 45% by weight of a therapeutically-active ingredient (see U.S. Patent '692, claim 24, current application, claims 1, 3, 6-8, 10-12, 21, 22, 24-26, 28, 29, and 31-35).

*Claim Rejections - 35 USC § 103*

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 4, 5, 9, 13, 14, 23, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eitenmuller et al. (U.S. Patent 4,610,692) in view of Pirhonen et al. (U.S. Patent Publication 2003/0104029 A1) and Santos, E. et al. (IDS document: AQ; J. Biomed. Mater. Res. 41(1): 87-94 (1998)).

The teachings of Eitenmuller et al. are set forth above. Eitenmuller et al. does not explicitly disclose a composition comprising either 1-methyl-2-pyrrolidone (NMP) and/or a bone morphogenetic protein (BMP).

Pirhonen et al. disclose a resorbable polymer composition comprising a base material including a polymer matrix or resorbable polymer or copolymer, and N-methyl-2-pyrrolidone (NMP), wherein NMP is present in an amount imparting osteogenic properties for the composition (see US 2003/0104029 A1, particularly claim 1).

Santos, E. et al. disclose a porous Si-Ca-P xerogel that can be used to provide a bioactive substrate for bone formation, and can be used as a vehicle for the controlled release of bioactive factors, such as BMP-2, a member of the BMP family (see page 93, last paragraph of Discussion section).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the

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very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). One would have been motivated to produce a composition comprising a porous carrier of glass material and at least one pyrrolidone along with a bone morphogenetic protein, because of the need to improve bone tissue regeneration. Therefore, it would have been obvious to the person having ordinary skill in the art to manufacture a composition comprising a porous carrier of glass material, N-methyl-2-pyrrolidone, and a bone morphogenetic protein, such as BMP-2, since both Pirhonen et al, and Santos, E. et al. disclose the osteogenic properties of N-methyl-2-pyrrolidone, and BMP-2, respectively (current application, claims 1-7, and 21-29, and 31-35).

17. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eitenmuller et al. (U.S. Patent 4,610,692) in view of Pirhonen et al. (U.S. Patent Publication 2003/0104029 A1) and Santos, E. et al. (IDS document: AQ; J. Biomed. Mater. Res. 41(1): 87-94 (1998)) as applied to claims 4, 5, 9, 13, 14, 23, 27 above, and further in view of Hall (U.S. Patent 6,730,129 B1).

Hall disclose the use of a biocompatible material made of a metal, titanium, for implant in bone that is coated with a calcium phosphate substance and at least one bone growth stimulating substance (see U.S. Patent '129, particularly claim 25).

One would have been motivated to use a metal scaffold, because the scaffold provides a wider range and choice of implants to satisfy different applications to facilitate various bone growths, such as soft bones, and hard bones (U.S. Patent '129, col. 2, lines 53-56). Therefore it

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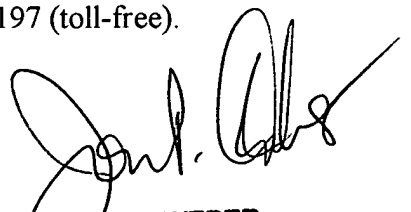
would have been obvious to the person having ordinary skill in the art to manufacture an implant comprising a metal scaffold, with a porous carrier of calcium phosphate and N-methyl-2-pyrrolidone along with BMP-2 to increase osteogenic properties of the implant (current application, claims 1-14, and 21-35).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 18, 2005



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**